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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,663	06/21/2001	Shantha Sarangapani	103.215.118	4750
23483	7590	12/01/2006	EXAMINER	
WILMER CUTLER PICKERING HALE AND DORR LLP 60 STATE STREET BOSTON, MA 02109			PAK, JOHN D	
			ART UNIT	PAPER NUMBER
			1616	
DATE MAILED: 12/01/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/886,663	Applicant(s) SARANGAPANI ET AL.	
	Examiner JOHN PAK	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2006 and 14 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7-9,11-13 and 15-20 is/are pending in the application.
 4a) Of the above claim(s) 1,2,4,7,8,11,12 and 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,9 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims 1-2, 4-5, 7-9, 11-13 and 15-20 are pending in this application. Claims 1-2, 4, 7-8, 11-12 and 15-20 stand withdrawn from further consideration as being directed to non-elected subject matter. Claims **5, 9 and 13** will presently be examined.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 9 and 13 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record, which reasons are expressly incorporated herein by reference. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 5, 9 and 13 recite various percentages, *many of them newly claimed*, for all the different invention components. Applicant's explanation of descriptive support for each of these features has been given full consideration but they were found unpersuasive.

(1) Applicant states for the following with respect to the deactivating formulation:

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5% of chemical deactivating formulation and 95% carrier. Support for this combination can be found on page 18, Example 5, where the composition is described as including ICET powder 76-69A or 76-69AA from Table II on pages 16-17 which makes up less than 5% of the composition. ICET powder 76-69AA would be the chemical deactivating formulation at a level of 3.03% and if combined with Dabco at a level of 1-3 % would make the percentage of the chemical deactivating formulation (76-69AA plus Dabco) to be between 4.03% and 6.03%. The carrier polymer at 95% + 76-69AA at 3% + Dabco at 1-3% create the composition. 5% is in the range of 3.03% and 6.03%

This is a perfect illustration of how out of line applicant's supposed descriptive support argument is. Even if all of applicant's arguments could be accepted, which no reasonable skilled artisan would, the best case scenario is 4.03% or 6.03% chemical deactivating formulation, **not 5%, as required by the claims.** 4.03% and 6.03% does not provide descriptive support for 5%.

As for the 95% carrier amount, applicant's descriptive support is absolutely in error. In the very Example 5 that applicant points to, the polymer carrier amount is 96.7% (Solucote 1068, which is a polyurethane coating substance) – see specification page 18. Applicant is completely without basis in asserting descriptive support.

(2) Applicant adds the following with respect to the upper range of the deactivating formulation and lower range of the carrier:

25% of the chemical deactivating formulation and 75% carrier. Support for this combination can be found on page 20 where 1.0gm of the powder from Table II (containing the chemical deactivating components) + 0.1g of TiO₂ + 0.4gm of citric acid for a total of 1.5gm is blended with 7.5gm of a carrier polymer. The Zn-hydroxypyridine-2-Thione is a biocide and belongs to the biocidal formulation. Thus the total weight of the chemical deactivating formulation is 1.5 gm. The plasticizer weight is adjustable, and 10 drops would be approximated to 0.5gm for this plasticizer based on its density). A total of 7.5 gms of carrier + 1.5 grams of the

chemical deactivation formulation additives makes the total weight of the composition 9 grams.

7.5 gm of the carrier polymer	= 83.3%
1.0 gm of powder from Table II	= 11.1%
0.1gm of TiO ₂	= 1.1%
0.4 gm of Citric acid	= 4.4%

If one decides keep the plasticizer at 0% as is the case in several examples, then one could add a maximum of 16.7% of the chemical deactivating formulation and the element in the claims has been amended to 16%.

Applicant's arguments are in error. Applicant is not even arguing the correct claim feature. The upper range of the chemical deactivating formulation has been amended by applicant to be 16 wt% and the upper range of the carrier has been amended by applicant to be 64 wt%. See the amendment of 4/27/2006.

(3) Applicant states the following regarding 0-10% titanium dioxide and 0-23% plasticizer:

0-10% of titanium oxide: Support for this limitation can be found on pages 20 and 37 where the formulations are shown to include titanium oxide in this range. Several formulations also do not include titanium oxide.

0-23% of the plasticizer: This limitation is disclosed on page 21 where, it state that the plasticizer amount in Example 6 is 23.08%; however, there is support on page 18 that the formulations could be added to a carrier polymer without any plasticizer. Thus, the range of 0-23% for the plasticizer.

Again, the argument is in error. Page 20 shows 0.1 g titanium dioxide + 1 g of an unidentified powder from Table II + 0.4 g citric acid + 0.5 g Zn 1-hydroxypyridine-2-thione + 10 drops of plasticizer. This does not provide descriptive support for 0% titanium dioxide. Moreover, this does not provide descriptive support for 0% titanium dioxide, which must be present in combination with 5-16 wt% chemical deactivating

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formulation (which contains the components set forth in the claims), 0-20 wt% plasticizer and 64-96 wt% carrier.

Page 37 shows 10.3% titanium dioxide in combination with a mixture that does not clearly delineate what exactly is the "chemical deactivating formulation." Hence, even if 10.3% could be argued as providing descriptive support for 10% titanium dioxide, descriptive support as a whole is lacking since the titanium dioxide is not disclosed in combination with components that satisfy the claim features in the instant claims, e.g. not disclosed in combination with 5-16 wt% chemical deactivating formulation. The presently claimed chemical deactivating formulation comprises nanosize metallic silver and compounds of Mo, Ag, Cu, V, Mn, Zn and Fe. However, if the chemical deactivating composition components listed in the Table bridging pages 36-37 are calculated, the following can be noted:

<u>Metal compounds of Mo, Ag, Cu, V, Mn, Zn, Fe</u>	<u>Nanosize silver</u>
1.4% silver phosphate	2.6%
10.3% CuO	
2% Ferric oxide	
1.3% ZnO	
1.3% silver citrate	
1.3% silver salicylate	
5.2% or 5.1% silver phosphate	
2% copper (II) phthalocyanine	
optional 0.2-3% zinc pyrithione	
<hr/>	
Total: minimum 24.7% + 2.6% = minimum 27.3%	

As a result, the 10.3% titanium dioxide in the table is in combination with an amount of components that do not correspond to the claim requirements (i.e. 27.3% is much

higher than the claim-required 5-16%). The disclosure on pages 36-37 therefore fails to provide the descriptive support that applicant is arguing.

Applicant's arguments for the support of the plasticizer amount is defective for similar reasons. Out of context numbers are used, and even if applicant's numbers were accepted for argument sake, they are still deficient in providing the descriptive support for the presently claimed combination of ingredients.

(4) Applicant states the following on pages 9-10 of the 4/27/2006 response.

Chemical deactivating formulation:

(a) At least 25% of Metallic Silver-copper alloy and silver of nanosize (1-100nm).

The "nanosize" is defined on page 16 as 1-100nm. In Example 4 on page 16, nanosize silver is listed as a chemical deactivating filler. Under Example 4, in Table II the nanosilver is 27.5% of the chemical deactivating formulations 76-69A and 76-69AA.

Applicant's statement is inaccurate. 27.5% is not descriptive support for 25%.

(b) At least 66% by weight of metal compounds selected from the group consisting of copper, molybdenum, silver, vanadium, manganese, zinc and iron.

All of these materials are identified on page 16 -17 as being chemical deactivating fillers. Under Example 4, Table II, the formulations 76-69A and 76-69AA where the components are as follows:

	<u>69A</u>	<u>69AA</u>
Silver phosphate (silver compound)	= 22.5%	-
CuO (nano)	= 25%	23.25%
Ferric oxide	= 12.5%	12.5%
Zinc Oxide	= 12.5%	12.5%
Silver citrate	= -	22.5%
Copper (I) oxide	= -	1.75%
	<hr/> 72.5%	<hr/> 72.5%

Applicant's statement is inaccurate. 72.5% is not descriptive support for 66%.

(c) **0-5 % of organic tertiary amine:** Support for the limitation on page 37 where the use of 5% of organic tertiary amine is disclosed.

(d) **0-4% citric acid:** Support can be found on page 20 where 0.4 grams of citric acid is incorporated into the formulation.

Applicant's arguments for the descriptive support for the (c) and (d) amounts is defective for similar reasons. Out of context numbers are used, and even if applicant's numbers were accepted for argument sake, they are still deficient in providing the descriptive support for the presently claimed combination of ingredients. For example, the supposed **5% organic tertiary amine** disclosed on page 37 is a specious argument because the 10.3% titanium dioxide and 45% butylparaben must be taken out of the calculation since those are not part of the chemical deactivating formulation. The recalculated percentage would thus be much higher. Additionally, the supposed support for **0-4% citric acid** is similarly illusory. Page 20 discloses 0.4 g citric acid in admixture with 1.5 g of substances that could be considered part of the chemical deactivating formulation (1 g "powder from example" + 0.5 g Zn 1-hydroxypyridine-2-thione). Thus, the 0.4 g citric acid there actually represents 21% of the total components that could be considered to be present in the chemical deactivating formulation.

(5) Applicant continues to pick and choose out of context and totally different compositions to provide some sort of arbitrary numerical support for the instantly

claimed features:

Antimicrobial Composition.

(a) **4-25% of an antimicrobial formulation:** Support for the 4% portion of this limitation is found on page 18, in Example 5, where 3.03% of the ICET powder from Table II is described. Therefore the applicant claims the percentage of the antimicrobial formulation to be at least the 4% minimum.

Now applicant wants the powder in Example 5 to be used for providing descriptive support for the “antimicrobial formulation.” In (1) above, applicant argued that the same example stood for the “chemical deactivating formulation.” This is exactly supportive of the Examiner’s position – applicant failed to adequately disclose the now-claimed organization of the claimed components (let alone the specific percentages) as “chemical deactivating composition,” “chemical deactivating formulation,” “antimicrobial composition,” and “antimicrobial formulation.” The same Example 5 on page 18 cannot possibly be used to provide descriptive support for both “chemical deactivating formulation” and “antimicrobial formulation,” because the maximum nanosize silver in the antimicrobial formulation is 20.5 wt%, whereas the nanosize silver in the chemical deactivating formulation is at least 25 wt%. Besides, 3.03% does not provide descriptive support for 4%.

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Applicant further argues:

Support for the upper end 25% limitation of the antimicrobial formulation in the composition and 75% carrier can be found on page 20, where the antimicrobial formulation is described as including 1.0gm of the powder from Table II (containing the antimicrobial (or biocidal) components as per the description of components on page 16 under Example 4), plus 0.1gm of TiO₂ plus 0.4gm of citric acid for a total of 1.5gm of the antimicrobial formulation which is blended with 7.5gm of a carrier polymer and 0.5 gm of Zn-hydroxypyridine-2- thione (zinc pyrithione). The plasticizer weight in this example is .55gm as its density is 1.1gm/ml for a total weight of the formulation of 10.05gms.

7.5 gm of the carrier polymer	= 75%
1.0 gm of powder from Table II	= 10%
0.1gm of TiO ₂	= 1%
0.5gm of Zn pyrithione	= 5%
Citric acid	= 4%
Plasticizer	= 5.5%.

Depending on the formulation one chooses, for example, powder 76-69AA is predominantly chemical deactivating while 76-69BB is predominantly an antimicrobial.

This is perhaps the most confused argument so far. To get to the 25% antimicrobial formulation descriptive support, applicant somehow asks to stretch the supposed 10% to encompass 25%. The TiO₂, Zn pyrithione, citric acid and plasticizer are not part of the claimed "antimicrobial formulation." See claims 5 and 13. Additionally, 75% carrier is not currently being claimed for the antimicrobial composition.

(6) Applicant further argues regarding the antimicrobial composition:

(b) **.2 - 5 % of Zinc pyrithione.** This term is synonymously referred to as Zinc, 1-hydroxypyridine-2-thione in the application, and it is described as a biocide on page 17 of the application and is indicated in the Table II as an ingredient that can be added to the antimicrobial formulation.

.2% zinc Pyrithione is supported by the disclosure on page 17. Support for 5% of zinc pyrithione can be found on page 20, Example 6 where the zinc pyrithione could be added to amount to 5%.

The Examiner reiterates that applicant failed to adequately disclose the now-claimed organization of the claimed components (let alone the specific percentages) as “chemical deactivating composition,” “chemical deactivating formulation,” “antimicrobial composition,” and “antimicrobial formulation.”

Specifically here, the 0.2-5 wt% zinc pyrithione must be present in combination with 4-25 wt% of the presently claimed “antimicrobial formulation.” The presently claimed antimicrobial formulation requires 5-20.5 wt% nanosize silver or silver/copper alloys and 15-48 wt% oxides, phosphates, citrates and salicylates of Ag, Cu, Zn and Bi in relative proportions. Table II, which appears on pages 16-17, fails to show any composition that meets this requirement. 76-69A and 76-69AA both contain nanosize silver at 27.5%, which is too high for the “antimicrobial formulation.” 76-69B, 76-69BB, 76-108-01 and 76-114-01 have the following defects relative to the instant claims: the concentration of the “antimicrobial formulation” is too high. Note that the claims require 4-25 wt% antimicrobial formulation. Also note that the claimed antimicrobial formulation contains nanosize silver or silver/copper alloys and oxides, phosphates, citrates and salicylates of Ag, Cu, Zn and Bi. 76-69B, 76-69BB, 76-108-01 and 76-114-01 contain such components that add up to far more than 25 wt%. Therefore, none of the zinc pyrithione disclosure is effective descriptive support for the claims since all of applicant’s arguments ultimately refer back to the Table II on pages 16-17.

(7) The rest of applicant’s arguments fail for the same or analogous reasons. The originally filed disclosure failed to adequately disclose the now-claimed organization

of the claimed components (let alone the specific percentages) as “chemical deactivating composition,” “chemical deactivating formulation,” “antimicrobial composition,” and “antimicrobial formulation.” None of applicant’s explanations provide sufficient descriptive support for the claimed feature in the context of the presently claimed invention as a whole, as discussed above.

For these reasons, the claims must again be rejected as lacking in adequate descriptive support.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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